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February 28, 2006

**VIA EFILING**

The Hon. Kent A. Jordan  
USDC for the District of Delaware  
844 King Street  
Wilmington, DE 19801

**RE: In Re: '318 Patent Infringement Litigation,  
C.A. No. 05-356 (KAJ) (consolidated)**

Your Honor:

My firm, along with Rakoczy Molino Mazzochi Siwik LLP, represent Defendants Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc., in the above-captioned consolidated litigation. We write pursuant to Local Rule 7.1.2(c) to bring to the Court's attention the recent decision in *UCB Societe Anonyme v. Mylan Laboratories, Inc.*, No. 04-cv-683-WSD (N.D. Ga.) (a copy of which is attached hereto), in connection with Mylan's pending Rule 12(c) Motion for Judgment on the Pleadings Dismissing Plaintiffs' Willful Infringement Claim or, in the Alternative, to Bifurcate and Stay Discovery on Such Claim (D.I. 57-59, 85).

Mylan has moved to dismiss Plaintiffs' willful infringement claim because Plaintiffs base their claim solely on Mylan's ANDA filing and Paragraph IV certification. *UCB* is an ANDA case from the U.S. District Court for the Northern District of Georgia in which the court dismissed Plaintiffs' willful infringement claim pursuant to Fed. R. Civ. P. 12(c). In *UCB*, the district court applied *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004) to conclude that "UCB's allegations cannot support a claim of willful infringement" based upon the defendants' filing of an ANDA containing a Paragraph IV certification. (Order at 6-7). The court noted that in *Glaxo*, "the controlling authority on this issue," the filing of "an ANDA was a 'highly artificial' act of infringement, giving 'rise to only a limited set of statutorily-defined consequences set forth in 35 U.S.C. § 271(e)(4),' and as such, "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." (*Id.* at 6).

As in *UCB*, Plaintiffs here have alleged that Mylan had notice of the patent at issue and that Mylan's infringement was willful. (*See* Order at 5). The *UCB* court held that "the

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only act of infringement alleged in UCB's complaint is Defendants' filing of an ANDA and an allegedly baseless paragraph IV certification," and, accordingly, "Defendants are entitled to judgment on the pleadings on UCB's claims for willful infringement." (*Id.* at 6-7 (citing *Aventis Pharma Deutschland GMBH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586, 592 (D. Mass. 2005))). Here, as in *UCB*, Plaintiffs' claim should be dismissed.

For the foregoing reasons, Mylan respectfully requests that the Court accept Mylan's citation of additional authority as support for Mylan's Rule 12(c) motion for judgment on the pleadings with respect to Plaintiffs' willful infringement claim.

Respectfully,

A handwritten signature in black ink, reading "Mary Matterer". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Mary B. Matterer

Attachments

cc: Attached Service List (via email)

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION**

**UCB SOCIETE ANONYME, and  
UCB PHARMA, INC.,**

**Plaintiffs,**

**v.**

**1:04-cv-683-WSD**

**MYLAN LABORATORIES, INC.,  
et al.,**

**Defendants.**

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**ORDER**

This matter is before the Court on Defendant Cobalt Pharmaceuticals, Inc.'s Rule 12(c) Motion for Judgment on the Pleadings Dismissing Plaintiffs' Willful Infringement Claims [76] and Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.'s Rule 12(c) Motion for Judgment on the Pleadings Dismissing Plaintiffs' Willful Infringement Claims [112].

**I. BACKGROUND**

These are patent infringement actions involving UCB Societe Anonyme and UCB Pharma, Inc.'s (collectively "UCB") epilepsy drug Keppra, containing the active ingredient levetiracetam. Keppra was approved by the Food and Drug

Administration (“FDA”) based upon a New Drug Application (“NDA”) filed by UCB. UCB holds U.S. Patent Nos. 4,837,223 (the “223 patent”) and 4,943,639 (the “639 patent”) for this drug. Defendants Cobalt Pharmaceuticals, Inc., Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively “Defendants”) filed an abbreviated new drug application (“ANDA”), seeking approval by the Food and Drug Administration (“FDA”) to market a generic version of Keppra.<sup>1</sup> In their paragraph IV certification, submitted as part of their ANDA, Defendants claim UCB’s patents are invalid and will not be infringed by the generic drugs.

Defendants have not yet sold their generic drug products.

In response to Defendants’ filing of an ANDA and paragraph IV certification, UCB sued Defendants for infringement of its patents. UCB claims

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<sup>1</sup> Congress created the ANDA procedure to allow generic drug companies to seek FDA approval for the manufacture and sale of generic drugs. Under this procedure, a company may file an ANDA for FDA approval to market a generic version of a previously-approved new drug application, notifying the patent holder of the ANDA application. After such filing, a district court has jurisdiction under 35 U.S.C. § 271(e)(2) for a patent-infringement action before the ANDA drug has been marketed to determine if the patent is valid and if the generic drug would infringe the patent. An ANDA applicant must address patents covering the drug by filing one of four certifications. *See* 21 U.S.C. § 355(j)(2)(A)(I)-(IV). Defendants here filed a “paragraph IV certification,” stating UCB’s patents are invalid or will not be infringed by the generic drug.

Defendants' "statement of the factual and legal bases for its opinion regarding the validity" of the patents "is devoid of an objective good faith basis in either the facts or the law." (Mylan Compl. ¶¶ 26-27, 43-44; Cobalt Compl. ¶¶ 25, 42.) As a result, UCB claims Defendants are liable for willful infringement of its patents, and that this case is "exceptional."

Defendants move the Court to enter judgment on the pleadings dismissing UCB's willful infringement claims pursuant to Federal Rule of Civil Procedure 12(c). Defendants claim UCB's sole basis for these claims -- that Defendants filed an ANDA and a baseless paragraph IV certification -- is insufficient to support its claims of willful infringement.

## **II. DISCUSSION**

"A motion for judgment on the pleadings is subject to the same standard as is a Rule 12(b)(6) motion to dismiss." Provident Mut. Life Ins. Co. of Philadelphia v. City of Atlanta, 864 F. Supp. 1274, 1278 (N.D. Ga. 1994). On a motion for judgment on the pleadings, the allegations contained in the complaint must be accepted as true and the facts and all inferences must be construed in the light most favorable to the nonmoving party. See Hawthorne v. Mac Adjustment, Inc., 140 F.3d 1367, 1370 (11th Cir. 1998). A "complaint should not be dismissed for

failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” Conley v. Gibson, 355 U.S. 41, 45-46 (1957).

Because UCB’s only basis for its claims of willful infringement is that Defendants filed an allegedly baseless ANDA and paragraph IV certification, Defendants argue that UCB’s allegations cannot support a claim for willful infringement and must be dismissed under Rule 12(c). Defendants claim the ANDA procedure is an artificial act of infringement, created by Congress, to allow parties to litigate patent infringement claims before the generic manufacturer actually markets the generic drugs. Recognizing the artificial nature of such infringement, Defendants claim the Federal Circuit has held the mere filing of an ANDA application and certification cannot support a claim for willful infringement. (Def. Cobalt’s Mot. for J. on Pleadings at 7; Mylan Defs.’ Mot. for J. on Pleadings at 5.) See also Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1350-51 (Fed. Cir. 2004); Aventis Pharma Deutschland GMBH v. Cobalt Pharms., Inc., 355 F. Supp. 2d 586 (D. Mass. 2005).<sup>2</sup>

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<sup>2</sup> Defendants Cobalt and Mylan filed notices of filing additional authority [140, 154, 155], citing two additional cases in which district courts dismissed willful

UCB argues it alleges Defendants were “aware of the ‘223 and ‘639 patents when it filed its ANDA.” (UCB’s Opp’n to Def. Cobalt’s Mot. for J. on Pleadings at 7.) UCB further alleges Defendants’ statements regarding the factual and legal bases for their opinion regarding the validity of the patents are “devoid of an objective good faith basis in either the facts or the law,” and UCB’s willful infringement claim “is based on Cobalt’s wholly unjustified assertions in its certification letter, its failure to satisfy its obligations of due care, and its reliance on those arguments in this litigation.” (*Id.*)<sup>3</sup>

The issue before the Court is whether UCB can base its claims of willful infringement on its allegations that Defendants filed an ANDA and objectively

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infringement claims in similar cases.

<sup>3</sup> UCB also contends the Court may award attorneys’ fees under the “exceptional case” standard based on the totality of the circumstances, with or without a finding of willful infringement. (UCB’s Opp’n to Def. Cobalt’s Mot. for J. on Pleadings at 8 (citing Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1346-47 (Fed. Cir. 2000).) UCB argues the Federal Circuit held “the [Hatch-Waxman] Act unambiguously permits an award of attorney fees to the prevailing party in exceptional cases *on the basis of an ANDA filing.*” (*Id.*) An award of attorneys’ fees upon a finding that a case is “exceptional” is to be distinguished from a finding of willful infringement. See Glaxo, 376 F.3d at 1350 (“[I]n Yamanouchi, we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney’s fees was permitted because . . . unjustified litigation and misconduct has always justified a finding of an exceptional case.”).

baseless paragraph IV certifications. Glaxo is the controlling authority on this issue. In Glaxo, the district court found defendant's filing of an ANDA without a reasonable basis for believing its product would not infringe the patent constituted an act of willful infringement, and awarded plaintiff attorneys' fees. The Federal Circuit reversed the district court's award of attorneys' fees. The court found that filing an ANDA was a "highly artificial" act of infringement, giving "rise to only a limited set of statutorily-defined consequences set forth in 35 U.S.C. § 271(e)(4)." Glaxo, 376 F.3d at 1349. The court stated, "as suggested by Yamanouchi, we now hold that the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." Glaxo, 376 F.3d at 1350-51.<sup>4</sup>

In this case, the only act of infringement alleged in UCB's complaint is Defendants' filing of an ANDA and an allegedly baseless paragraph IV certification.

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<sup>4</sup> The court expressly held that attorneys' fees may be awarded to the prevailing party in "exceptional cases" pursuant to 35 U.S.C. § 285, and that the filing of a baseless paragraph IV certification in an ANDA filing, "when combined with litigation misconduct, warranted an exceptional case finding." Glaxo, 376 F.3d at 1350 (citing Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1346 (Fed. Cir. 2000)).



The Federal Circuit has spoken clearly on this issue. Applying Glaxo to the facts of this case, and viewing the allegations as true and in the light most favorable to UCB, UCB's allegations cannot support a claim of willful infringement.

Accordingly, Defendants are entitled to judgment on the pleadings on UCB's claims for willful infringement.<sup>5</sup> Accord Aventis Pharma Deutschland GMBH v. Cobalt Pharms, Inc., 355 F. Supp. 2d 586, 592 (D. Mass. 2005) (granting defendant's motion for judgment on the pleadings on plaintiff's willful infringement claim).

### III. CONCLUSION


For the reasons state above,

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<sup>5</sup> Defendants' filing of a baseless ANDA certification may permit an award of attorneys' fees as part of a finding that this case is exceptional. See Yamanouchi, 231 F.3d at 1347 (noting the "trial court need not have elevated the ANDA certification into a finding of willful infringement," but finding "a case initiated by a paragraph (2) filing, like any other form of infringement litigation, may become exceptional if the ANDA filer makes baseless certifications"); Aventis Pharma Deutschland GMBH v. Lupin, No. 2:05CV421, 2006 WL 141670, at \*6 (E.D. Va. Jan. 18, 2006) ("[A] district court may not 'elevate' an ANDA certification, *even if it is 'baseless,'* into a finding of willful infringement for the purposes of attorney's fees; rather, a baseless ANDA certification accompanied by litigation misconduct may result in an award of attorney's fees because such conduct constitutes an 'exceptional case.'").

**IT IS HEREBY ORDERED** that Defendant Cobalt Pharmaceuticals, Inc.'s Rule 12(c) Motion for Judgment on the Pleadings Dismissing Plaintiffs' Willful Infringement Claims [76] and Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.'s Rule 12(c) Motion for Judgment on the Pleadings Dismissing Plaintiffs' Willful Infringement Claims [112] are **GRANTED**.

**SO ORDERED**, this 28th day of February, 2006.

  
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WILLIAM S. DUFFEY, JR.  
UNITED STATES DISTRICT JUDGE

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